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THE PHARMACISTS' AND PATIENTS' SIDE OF POLICY MEASURES IN PHARMACEUTICAL MARKETS: THE EFFECTS OF CHANGING PHARMACY MARGINS

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OBJECTIVES: Under current economic and financial framework, some important revisions were made to the National Pharmaceutical Policy in Portugal, aimed at decreasing prices and contributing to lower public expenditure in the Health Sector. The Decree-Law 112/2011 introduced a new margin system both for pharmacies and wholesalers. A linear margin scheme, expressed as a percentage mark-up on the consumer price before VAT was thus replaced by a regressive system combining: i) a fixed fee that increases with the ex-factory price of drugs; ii) a regressive margin expressed as a percentage of the ex-factory price. This paper aims to assess: costs associated to the pharmacy dispensing and other pharmacy services provided; the proportion of purchased medicines on total prescribed; the perception of pharmacists and patients regarding changes in access to medicines, namely possible shortages of medicines in Portuguese pharmacies, and other issues. **METHODS:** In order to access the effects of this policy measure, surveys were carried out to consumers and pharmacies across the country. Four surveys were administered in week 25 to 29 June: survey to Pharmacy Owner; survey following each prescription sale (one day census); survey about pharmacy services not associated to the dispensing of medicines (5-day census). Pharmacists were also requested to administer a survey to patients presenting a prescription. **RESULTS:** To be completed after analysis of the surveys (after 29 June) **CONCLUSIONS:** We will elaborate on a more efficient distribution of medicines in view of both the economic sustainability of pharmacies and the impact on patients.

HEALTH CARE USE & POLICY STUDIES - Risk Sharing/Performance-Based Agreements

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TRENDS IN THE USE OF HEALTH ECONOMIC DATA TO INFORM GLOBAL MARKET ACCESS DECISIONS: PRELIMINARY RESULTS FROM AN ONLINE SURVEY

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OBJECTIVES: To explore opinions among professionals in health economics and related fields on global trends in the use of health economic (HE) data in various market access decision-making processes. **METHODS:** An on-line survey was administered to professionals who work with HE data. The survey captured professional background characteristics and respondents' opinions on trends in the role of HE data in various decision-making areas and specifically in applying HE analysis to individualized medicine and orphan medications. **RESULTS:** Seventy three professionals completed the survey; 53% from Europe, 30% United States, and 16% from other countries. 25% were from the pharmaceutical/medical technology industry, while 75% were from academia/government and other institution types. The area where most respondents expected an increasing role for HE data was in reimbursement decisions (89%), followed by manufacturers' internal pricing (78%), clinical guideline development (70%), and clinical practice (59%). Opinions on whether cost-effectiveness analysis of individualized medicine will become a dominant approach in the next three years varied widely with 49% of respondents in agreement and 19% disagreeing. Equally, 37% of the respondents agree and 37% disagree that orphan drugs should be subjected to the same value-based assessments as other products, with 26% being neutral. **CONCLUSIONS:** While there is strong agreement that the role of HE data will increase in the areas of pricing, reimbursement, clinical guideline development and clinical practice, there remains some disagreement about how specific HE approaches and policies will be applied in the near future. Further research is warranted to better understand the use of HE data in market access decision making globally.

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PHARMACOVIGILANCE AND THE CASE STUDY OF VIOXX

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OBJECTIVES: Pharmacovigilance as a part of drug safety surveillance consists in collecting and analysing adverse effects reports and is intended to evaluate the safety of medicinal products and to eliminate drugs whose risks outweigh therapeutic benefits. The research aims were: to recognize the rules of current pharmacovigilance practices, to examine their capacity to effectively manage public health and to propose an improved pharmacovigilance model. **METHODS:** The rules of drug safety monitoring in the United States, Canada, the UK and Poland have been presented, analysed and compared. In order to assess the effectiveness of the respective national practices, an additional analysis covered reports prepared by health care professionals, consumers and MAHs, submitted to the responsible health care agencies (FDA, Health Canada, MHRA and URPL, WMiPB). Based on the results, an improved pharmacovigilance model was proposed. A case study of VIOXX® was used to review different pharmacovigilance practices by analysing reports on this recalled drug, including the incidence and type of adverse effects reported, principles of pharmacovigilance signal detection and measures, taken by the agencies. The model was then subject to final evaluation. **RESULTS:** The analysed pharmacovigilance practices allowed to collect sufficient data on adverse effects, but none of the agencies raised any alarm addressing safety issues before the product was recalled by the manufacturer. **CONCLUSIONS:** The procedures underlying pharmacovigilance practices need to be amended by adopting the ideas proposed in the model, especially in the area of data analysis and signal detection, for instance: rigorous five-year safety monitoring of new products, especially post-marketing surveillance; publicly available adverse effects reports collected by the agencies; publicly available standards of signal detection based on MAHs declarations in SPCs; and including clinical trials' analysis in standard drug safety monitoring.

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FUNDING THE UNFUNDABLE: THE AUSTRALIAN APPROACH FOR SPECIALTY PHARMACEUTICALS

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OBJECTIVES: Specialty drugs are high-cost drugs for treating complex chronic conditions, such as cancer and autoimmune disorders. Most are biologics, and they provide highly targeted treatment for which there are few other viable treatment options, but at prices that are substantially higher than traditional medications. This study examines how Australia funds specialty pharmaceuticals under its publicly funded, national drug coverage system. **METHODS:** Review of the literature and analysis of prescription volume and expenditures (2010-2011). **RESULTS:** Inherent in all decisions on coverage of new health technologies is uncertainty, arising from the absence of complete information about comparative (long-term) effectiveness, incremental cost-effectiveness, adoption and diffusion, and economic impact. Uncertainty is more pronounced for specialty drugs due, in part, to their high cost. In response, Australia created a Complex Authority Required Highly Specialized Drugs Program under the Pharmaceutical Benefits Scheme to fund and deliver specialty drugs. This program currently includes 34 drugs (e.g. adalimumab, etanercept, imatinib). Subsidized access to these drugs is restricted to subsets of patients who must show evidence of the clinical need (e.g. pathology report to confirm the diagnosis) and whose condition is inadequately controlled by existing, less expensive therapies. For continued access to many of these agents, patients must also demonstrate adequate clinical improvement; clinical outcomes are evaluated according to predetermined quantifiable criteria. Because of the availability of multiple effective agents for a single clinical indication (e.g. rheumatoid arthritis), Australia was the first country to establish an 'interchangeability rule' under a publicly funded system that allowed eligible patients to trial an alternate medicine without the need to re-qualify against the initial criteria. Analysis is underway to assess the current status of this program, including uptake and economic impacts. **CONCLUSIONS:** Australia has created an innovative funding approach to balance the benefits, risks, and costs of specialty pharmaceuticals.

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TRENDS IN THE USE OF INNOVATIVE CONTRACTING MODELS BETWEEN THE PHARMACEUTICAL INDUSTRY AND PAYERS IN EUROPE

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OBJECTIVES: To provide an overview of past and current models and practices in innovative contracting in Germany, the UK, Sweden, Italy and France. Another aim was to uncover the experiences of different stakeholders with innovative contracting in Germany and the UK. **METHODS:** A comprehensive literature search on innovative contracting from 2008 onwards was performed. Information on the country involved, drug type, characteristic of the therapeutic area, timeframe, terms of the agreement and stakeholders involved was extracted. Interviews with 22 stakeholders from Germany (n=14) and the UK (n=8) were conducted. Stakeholders included pharmaceutical company staff, payers, medical practitioners, governmental bodies and academics. **RESULTS:** The countries showing the highest activity in the use of innovative contracting were the UK (23 from 60 contracts), followed by Sweden (15/60) and Italy (10/60). Most schemes were applied to oncology drugs (29/60). The most frequently mentioned innovative contract model in the literature was the Coverage with Evidence Development (CED) scheme (23/60). From the interviews, it was observed that most stakeholders applied these schemes mainly to arrange broad market access, and were successful in their implementation (32%). Where stakeholders avoided innovative contracting schemes, this was due to their complexity, high administrative burden, and uncertainty of its benefits, particularly for payers. The high administrative burden was regarded as the greatest pitfall of innovative contracting schemes, being mentioned by 45% of the stakeholders. For the future, they prefer the use of simple rebate schemes. **CONCLUSIONS:** Innovative contracting provides a valuable tool for new innovative pharmaceuticals to gain market access whilst keeping the impact on payers' budgets under control. These schemes have not yet gained widespread acceptance, and stakeholders in the UK and in Germany are suspicious as to their benefit and their future relevance. Systematic research is needed to allow for the evaluation of these schemes.

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GLOBAL PHARMACEUTICAL RISK-SHARING AGREEMENT TRENDS IN 2011 AND 2012: SLOWING DOWN?

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OBJECTIVES: It would appear that ongoing economic austerity would lend itself to cost containment in health care through a natural increase in use of pharmacoeconomic strategies in general, and risk-sharing agreements in particular. How-

ever, many governments are forsaking such tactics to focus on shorter-term quick fixes. Whilst recognising that risks-sharing agreements represent an important market access strategy, the objective of this research was to examine if the marked expansion in number of risk-sharing agreements through 2007-2010 is still continuing, or if there is a gradual levelling off across the world. **METHODS:** Secondary research was conducted examining reimbursement decisions around the world, with a special focus on Australia, Belgium, Brazil, Canada, China, France, Germany, Hungary, Italy, The Netherlands, New Zealand, Poland, Russia, Spain, Turkey, UK and United States. This was supplemented by primary research with payors and organisations through interviews in native languages to identify potential risk-sharing agreements outside the public domain as well as general opinions. **RESULTS:** Thirty-two new risk-sharing agreements were found in the period of review (May 2011 - May 2012), which is roughly in-line with the rate found in previous years. The number of new drugs with risk-sharing agreements attached to them actually declined, and most new agreements are being negotiated for drugs which already have one in place. The majority of agreements tend to be finance-based, although new performance-based agreements continue to emerge, including in emerging markets. The majority continue to focus on the oncology arena. **CONCLUSIONS:** Although risk-sharing continues to be a routine part of market access in many countries, there appears to be a notable "levelling off" of the rapid expansion of this strategy in previous years. This is relatively unsurprising as it reaches a natural plateau, but still notable against the background of ongoing global austerity.

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IMPACT OF A FINANCIAL RISK-SHARING SCHEME ON BUDGET-IMPACT ESTIMATIONS: A GAME-THEORETIC APPROACH

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OBJECTIVES: As part of the process of updating the National List of Health Services (NLHS) in Israel, both health-plans ('payers') and manufacturers provide estimates on the expected number of patients that will utilize the drug. Currently, payers face major financial consequences when actual drug utilization is significantly higher than the allocated budget. We suggest a risk-sharing model that imposes a potential penalty on the two stakeholders; if the actual number of patients exceeds the manufacturer's prediction, the manufacturer will reimburse the payers by a rebate rate of α from the deficit. In case of under-utilization, payers will refund the government at a rate of γ from the surplus budget. Our study objective was to identify the optimal early estimations of both 'players' prior to and after implementation of the risk-sharing scheme. **METHODS:** Using a Game-Theoretic approach, in which both players' statements are considered simultaneously, we examined the impact of risk-sharing within a given range of rebate proportions (α, γ), on players' early budget estimations. **RESULTS:** With no risk-sharing, manufacturers and health-plans will choose to announce the smallest and highest number of patients, from the cumulative distribution function of patients, respectively. When increasing "α" to be over 50%, manufacturers will announce a larger number and health-plans will announce a lower number of patients than they would without risk-sharing, thus, substantially decreasing the gap between their estimates. On the other hand, increasing γ changes players' estimates only slightly. **CONCLUSIONS:** In reaction to applying a substantial risk-sharing rebate "α" on the manufacturer, both players are expected to adjust their budget estimates towards an optimal equilibrium. Since manufacturers do not benefit directly from the health-plans' rebate to the government, increasing α is a better vehicle for reaching the desired equilibrium rather than increasing γ, as both players are substantially influenced by the manufacturer's rebate α.

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RECENT GLOBAL INSIGHTS INTO RISK SHARING AGREEMENTS: A COMPARATIVE ANALYSIS

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OBJECTIVES: To evaluate whether risk sharing agreements (RSA) are utlilised by health technology assessment (HTA) agencies over the world. Similarities and differences between appraisals where an RSA is applied will be assessed across the different agencies. **METHODS:** Nine select HTA agencies across the globe (MOHTLC, NICE, PBAC, SMC, TLV, INESSS, CADTH, NCPE, and AWMSG) were scanned to determine what type of RSAs were adopted for drug appraisals. Only single technology appraisals published between 2010 and April 2012 were included in the search. Comparisons were made between the agencies to determine whether any common trends were present, particularly for appraisals on the same drug. **RESULTS:** In total 100 HTAs (74 treatments) were identified that included an RSA across the 9 agencies. The number of RSAs identified per agency was as follows: MOHTLC (24 HTAs), NICE (23), PBAC (15), SMC (14), TLV (10), INESSS (7), CADTH (6), NCPE (4), and AWMSG (2). Overall there was very little consistency between agencies as to which treatments included an RSA. For the very few treatments with an RSA fwith more than one agency, the type of agreement applied between these agencies varied. RSAs identified in NICE submissions were often elaborate whilst the remaining agencies usually applied simple discounts, price reductions or cost agreements. Interestingly, all recently submitted oncology therapies to INESSS were required to have a shared financial risk agreement for recommendation. **CONCLUSIONS:** RSAs are applied by several HTA agencies from around the world. There does not seem to be consistency in RSAs amongst the different agencies. If an RSA is made for a particular treatment for one agency, this does not mean an RSA will be applied by another agency for the same treatment.

HEALTH CARE USE & POLICY STUDIES - Conceptual Papers

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PAEDIATRIC USE MARKETING AUTHORISATION (PUMA): THE CHALLENGES OF COST-EFFECTIVENESS MODELLING WHERE LIMITED CLINICAL TRIAL INFORMATION IS AVAILABLE

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Paediatric use marketing authorisation (PUMA) was developed by the European Medicines Agency to promote the development of paediatric formulations of products that are already authorised but are no longer covered by intellectual property rights (patent, supplementary protection certificate). There are a number of aims of which 2 are of interest here: ensure that medicines used to treat children are subject to high-quality, ethical research and are appropriately authorised; and achieve these objectives without subjecting the paediatric population to unnecessary clinical trials and without delaying the authorisation for other patients. In September 2011 BUCCOLAM® was the first product to receive a PUMA for the treatment of prolonged, acute, convulsive seizures. Products approved in this way are likely to have less comparative data which makes both Pharmacoeconomic value demonstration and assessment more challenging. In order to undertake cost-effectiveness analyses for BUCCOLAM to inform HTAs, de novoprimary data gathering was required. This included: gathering expert views on treatment pathways, downstream consequences of seizures and utilities (utilising a Delphi process); gathering information on treatment pathways and the frequency and locale of seizures (patient/carer surveys); and a cost-gathering exercise with hospitals. The SMC and AWMSG were willing to accept the data gathered above in combination with extensive sensitivity analysis which addressed the economic uncertainties resulting from the limited clinical trial data. In other countries, where reimbursement is linked to the strength of efficacy evidence it can be very difficult for a PUMA product to demonstrate value. The PUMA process is relatively new and it may be necessary for HTA bodies to review their requirements for interventions licensed via this regulatory process and prepare an alternative pathway to assess their value. In many cases this approach has been taken for orphan and ultra-orphan diseases where the same data challenges may apply.

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WHY DO PATIENTS ENGAGE IN MEDICAL TOURISM?

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Medical tourism is commonly perceived and popularly depicted as an economic issue, both at the system and individual levels. The decision to engage in medical tourism, however, is more complex, driven by patients' unmet need(s), the nature of services sought and the manner by which treatment is accessed. In order to harness and promote the opportunities medical tourism offers, as well as address and contain attendant threats, an informed decision is crucial. This paper aims to enhance the current knowledge on medical tourism by isolating the types of decisions that patients make – and based on the existing literature, proposing a theoretical sequence in opting for or against medical care abroad. It proposes a sequential decision-making process to engage in medical tourism, which includes considerations of the required treatments, location of treatment, and the quality and safety issues that are attendant to seeking care. Where patient involvement is regarded as crucial in achieving the desired health outcomes and promoting the efficient use of resources, the active role of the patient under medical tourism should prove to be valuable. In consideration of the challenges and opportunities that medical tourism offers, bringing forward scholarship on the globalization of health care in general and of medical tourism in particular, calls for developing empirical evidence on this increasingly popular and complex form of accessing and provision of medical care.

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ADOPTION OF NEW TECHNOLOGIES IN TWENTY ESTABLISHED AND EMERGING MARKETS

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OBJECTIVES: The purpose of this analysis was to evaluate drivers affecting market access for new technologies in twenty established and emerging markets (Australia, Belgium, Brazil, Canada, China, Denmark, Finland, France, Germany, Italy, India, Japan, Norway, Poland, Russia, Spain, Turkey, the UK, Sweden, and Switzerland). **METHODS:** Health care spend, government debt ratio, financing structure and regulatory policy were examined relative to their impact on market access. Comprehensive reviews of publicly available literature, data sources, policies and regulations were performed for each country of interest. **RESULTS:** Entrants to markets without an official regulatory body face stiff competition from non-standard or counterfeit comparator products. At the other extreme, some countries require substantial country-specific clinical evidence for approval, making them cost-prohibitive for smaller manufacturers . High government debt ratios were found to be predictive of increased austerity measures, which broadly have a negative impact on market access for new technologies, placing pressure on downward pricing in countries that use national fee schedules. DRG-based systems were found to be more receptive than markets that reimbursed inpatient facilities through annual global payments. The likelihood of a medical device receiving an HTA in any country is dependent on (1) regulatory requirements for market entry and (2) the existence of device-focused HTAs, which are not as pervasive as HTAs for pharmaceuticals. In countries where inpatient procedures are funded by global payments, hospital level reviews are more likely than a national assessment for medical device technologies. In countries where fee-for-service dominates device